April 21, 1999

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William K. Hubbard
Associate Commissioner for Policy Coordination
Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98P-0504, Performance Standard for *Vibrio vulnificus*.

Dear Mr. Hubbard:

This letter is responding to the Federal Register request for information and views regarding eight specific questions related to the Center for Science in the Public Interest's (CSPI) petition to establish a standard for *Vibrio vulnificus* in raw molluscan shellfish of undetectable levels (Docket No. 98P-0504).

Taylor Shellfish Company is the largest producer of molluscan shellfish on the West Coast of the United States. The actions requested in the CSPI petition pose a major threat to the future of my company and the shellfish industry as a whole.

It is our belief that FDA should defer this issue to the Interstate Shellfish Sanitation Conference for deliberation. If FDA were to take unilateral action on this petition, circumventing the ISSC process, I would have to look seriously at whether we would continue as a company to be involved and support the ISSC. The Memorandum of Understanding in which FDA recognizes ISSC as the primary national organization to provide guidance on shellfish public health issues is a crucial foundation on which the effectiveness of the Conference is built.

In 1998, Issue 98-106 was submitted to the ISSC, which includes recommendations similar to those included in the CSPI petition. Conference delegates referred the issue to committee for further deliberation. This action was supported by the FDA along with a request for the committee to consider nine questions similar to the ones included in the FDA *Federal Register* Notice.

ISSC is in the process of finalizing a contract with Research Triangle Institute (RTI) to study the potential economic impact of establishing a performance standard of "non-detectable" for *Vibrio vulnificus*. The decision to conduct this study was the result of a recommendation by Mr. Phillip Spiller, Director, FDA Office of Seafood in his opening comments at the 1998 ISSC. The results of this study are crucial to any decision the ISSC or FDA could make regarding this issue.

The ISSC is working with FDA and State Shellfish Control Authorities in nine states to investigate levels of *Vibrio vulnificus* and *Vibrio parahaemolyticus* in shellstock in retail establishments. The results of these efforts will also be helpful to FDA and ISSC in their consideration of this issue.

98P-0504

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In light of the above ongoing efforts, it would seem most prudent for the FDA to either deny the petition as was requested by PCOGA in our December comments or to delay action until the results of these studies and recommendations regarding Issue 98-106 are available to FDA.

In response to the eight questions posed in the *Federal Register*:

1. Is the Ameripure Co. technology readily employable by the shellfish industry; if not, what barriers exist, and what steps could be taken to reduce or eliminate those barriers?

Whether the Ameripure technology is readily employable is not relevant if the finished product is not marketable. The marketability of Ameripure's finished product is unproven in PCOGA's opinion. This product is new to the market place and claims of acceptability by the proponent who stands much to gain through the sale of patent licenses and royalties are suspect. Continued application of the Ameripure process on a volunteer basis is appropriate and will ultimately determine market acceptability. Mandating the process on an entire industry could have devastating results if the product is in fact not acceptable to consumers accustomed to fresh, live, raw oysters on the half shell.

Assuming the Ameripure product were acceptable to the market, barriers that affect its employability include:

- Different treatment effectiveness for variable sized oysters, variable shell thickness, oyster species, cluster vs. single oysters, clams, mussels and scallops. To our knowledge, the Ameripure technology has not been proven effective on anything other than very uniform single Eastern oysters. The uniformity is apparently critical to the desired end result of "non-detectable" in all of the shellfish included in a particular pasteurization batch. The industry on all coasts harvest oysters of variable sizes. On the West Coast, there are a half dozen different species of oysters raised in a variety of culture systems which yield markedly different shell characteristics. Growers are concerned the Ameripure process will not accommodate the variability of their products.
- The resulting product is no longer live. It may taste similar to fresh, live raw oysters for the first few days following treatment, however the organoleptic characteristics are most certainly going to change over time compared to oysters still live in the shell. Shelf life will be reduced through the Ameripure process on some shellstock.
- Since the product is processed and no longer live shellstock, it has colder temperature (38° F) holding requirements than live oysters. Where Ameripure's product is marketed as being the same as live raw oysters, this will be confusing to the processing, distribution and retail sectors that will now have two different temperature regimes to follow for shellstock oysters.
- The cost of the patent license, royalties and processing equipment is not precisely known but is rumored to be high. I have heard the license to use the process could cost as much as $250,000 with a $0.02 per oyster royalty being paid to Ameripure. The equipment to process 40,000 pounds of product per day is rumored to cost as much as $800,000. These costs are prohibitive to even large companies like ours.

2. Other than the AmeriPure Co. process, what technologies, both present and anticipated, could significantly reduce the number of *V. vulnificus* in oysters while retaining the sensory qualities of a raw oyster? What is known about the ability of such technologies to reduce the number of *V. vulnificus* to nondetectable levels?

All the post-harvest technologies currently under study kill the animal, with the exception of irradiation, thereby changing the inherent condition of the product. Irradiation results in non-detectable levels without killing the live animal but is not approved by FDA. Freezing with liquid carbon dioxide results, reportedly, in levels approaching non-detectable. High hydrostatic pressure shows promise, but is still in the experimental stage. Short term depuration has proven ineffective in that it appears the Vibrios are part of the

normal bacterial flora of the shellfish and not readily shed and killed by disinfection systems employed in depuration. Longer term depuration may be effective but is not economical. Holding of animals in refrigerated sea water systems is a technique that may merit further review.

3. How reliable are such technologies? May they practically be required for an entire industry or a significant portion of that industry?

In that none of these other technologies has been proven and used extensively to produce shellfish with non-detectable levels of *Vibrio vulnificus*, it is not possible to assess their reliability. Freezing with liquid carbon dioxide is a well-established freezing technique for other food commodities. Its limited use for oysters appears to yield a quality product with characteristics similar to a fresh raw oyster if glazed and stored properly.

Depuration in itself is a reliable technology, but its application in reducing *Vibrio vulnificus* to non-detectable levels is not. Many West Coast oysters are marketed for the value of the flavors imparted by the particular growing waters. Depuration in a sterilized system, particularly for extended periods of time could eliminate these characteristics.

All of these other technologies require expensive equipment and would not be practical to impose on an entire industry or even a significant portion of the industry. The practicality of their application also is related to what species and product forms they are required to be applied to.

4. Would a performance standard have to be as low as ``non-detectable?" Do data exist that would permit the setting of a performance standard above ``non-detectable?" If so, at what level? Should the fact that *V. vulnificus* is found at low levels (less than 100 Most Probable Number/gram) in oysters in months (January and February) in which there have been no reported illnesses be taken into account when establishing a performance standard or level?

I question whether a performance standard is appropriate at all for an organism (*Vibrio vulnificus*) that is not "ordinarily injurious." For people in the at-risk group who choose to eat raw or raw-like product, a performance measure standard other than zero may be effective. For healthy individuals any performance standard would be ineffective and unnecessary.

If the ISSC determines a performance standard approach is appropriate, looking to months when there have been no historic reported illnesses or deaths attributed to *V. v.* could be valuable in determining what an appropriate level should be, particularly in that it is not practical to do feeding trials to establish an infectious dose.

5. Should a performance standard apply to all raw molluscan shellfish or only to oysters?

The vast majority of illnesses and deaths linked to *V. v.* have been attributed to oysters consumed raw. While, as mentioned, we question the validity of applying a performance standard to an organism that is not ordinarily injurious, it most certainly should not be applied to other types of shellfish. The suggestion that FDA may even be considering this has me very alarmed. We produce roughly 4,000,000 pounds of Manila clams and 1,000,000 pounds of mussels which have never been linked to *V.v.* illnesses or deaths. These products should not have to undergo post harvest treatment to reduce *V.v.*.

6. What would be the quantifiable and nonquantifiable costs of a performance standard? Who would bear the costs? What would be the effect on costs, and the distribution of costs, if there was only one, patented process that could be used to meet the performance standard? What would the effect on costs be if a standard of ``non-detectable" were put in place for all pathogens or for all raw molluscan shellfish?

This question is very broad and difficult to answer. The study commissioned by the ISSC to be done by RTI will attempt to quantify some of these economic impacts. FDA and ISSC should utilize the results of this survey in their deliberation of this issue.

If we processed only our live oysters under Ameripure's patent, the rumored royalty fees alone would cost us $20,000 annually. If shucked oyster meat were included that would raise the royalty fee another $360,000 annually. This does not include the cost of facilities and equipment and assumes customers would continue their current level of consumption with the treated oysters. From what I have heard regarding the market acceptability of this product, I doubt this will be the case.

A performance standard could likely eliminate live, raw shellfish as a consumer choice. Financial costs to processors, harvesters, distributors, retailers, foodservice operators and consumers would be substantial. Some of these will be quantifiable and others not. There would be a non-quantifiable socio-economic impact and cultural loss to consumers who have traditionally eaten raw shellfish.

7. What would be the quantifiable and nonquantifiable benefits of a performance standard? Who would enjoy the benefits?

There would be a benefit to a small group of vulnerable individuals from the at-risk population that could now choose to eat post harvest treated shellfish products with a reduced risk of illness from *Vibrio vulnificus*.

8. Another marine pathogen, *V. parahaemolyticus*, has caused over 700 reported cases of illness (gastroenteritis) during 1997 and 1998. There has been one death reported to the Centers for Disease Control and Prevention and several hospitalizations. Illnesses from *V. parahaemolyticus* have occurred from oysters harvested outside of the Gulf of Mexico region. Should a performance standard apply only to *V. vulnificus* or should it apply to other *Vibrio* species that post-harvest treatment might be able to reduce to nondetectable levels?

I believe that any adjustment to the existing performance standard of 10,000 MPN for *V. p.* should be considered separately from any deliberation concerning *V. v.*. The ISSC adopted an interim control plan for *V. p.* in 1998 for a three year period. The results of the effectiveness of the ICP will be evaluated at the 2001 ISSC Conference. Washington State implemented the *V. p.* ICP in the summer of 1998 and achieved significantly reduced illnesses compared to the previous summer with similar climatic conditions and ambient *V. p.* levels.

In closing, I appreciate your consideration of my comments on this important issue. I am dismayed however, that I am having to deal with it outside of the context of the ISSC. Participating in ISSC is already a significant cost and effort for my company. The FDA has a good record of cooperation and respecting the relationships established by the MOA. I urge you to continue that cooperative spirit and allow the Conference the opportunity to deliberate this issue.

Sincerely,

Bill Taylor

Bill Taylor
President

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